



## IN THE 22ND JUDICIAL CIRCUIT COURT OF CITY OF ST LOUIS, MISSOURI

Judge or Division: BRYAN L HETTENBACH	Case Number: 1522-CC11103
Plaintiff/Petitioner: ALVIN ADLER	Plaintiff's/Petitioner's Attorney/Address: JEFFREY J LOWE 8235 FORSYTH SUITE 1100 SAINT LOUIS, MO 63105
Defendant/Respondent: BOEHERING INGELHEIM PHARMACEUTICALS INC	Court Address: CIVIL COURTS BUILDING 10 N TUCKER BLVD SAINT LOUIS, MO 63101
Nature of Suit: CC Pers Injury-Prod Liab	(Date File Stamp)

**Summons for Personal Service Outside the State of Missouri  
(Except Attachment Action)**

The State of Missouri to: **BOEHERING INGELHEIM INTERNATIONAL GMBH**

Alias:

**PRINCIPAL PLACE OF BUSINESS  
BINGER STRASSE 173  
55216 INGELHEIM AM RHEIN  
GERMANY**

COURT SEAL OF



CITY OF ST LOUIS

You are summoned to appear before this court and to file your pleading to the petition, copy of which is attached, and to serve a copy of your pleading upon the attorney for the Plaintiff/Petitioner at the above address all within 30 days after service of this summons upon you, exclusive of the day of service. If you fail to file your pleading, judgment by default will be taken against you for the relief demanded in this action.

NOVEMBER 17, 2015

Date

Thomas Kloepfinger  
Circuit Clerk

Further Information:

**Officer's or Server's Affidavit of Service**

I certify that:

- I am authorized to serve process in civil actions within the state or territory where the above summons was served.
- My official title is \_\_\_\_\_ of \_\_\_\_\_ County, \_\_\_\_\_ (state).
- I have served the above summons by: (check one)
  - ☐ delivering a copy of the summons and a copy of the petition to the Defendant/Respondent.
  - ☐ leaving a copy of the summons and a copy of the petition at the dwelling place or usual abode of the Defendant/Respondent with \_\_\_\_\_, a person of the Defendant's/Respondent's family over the age of 15 years.
  - ☐ (for service on a corporation) delivering a copy of the summons and a copy of the petition to \_\_\_\_\_ (name) \_\_\_\_\_ (title).
  - ☐ other (describe) \_\_\_\_\_

Served at \_\_\_\_\_ (address)  
in \_\_\_\_\_ County, \_\_\_\_\_ (state), on \_\_\_\_\_ (date) at \_\_\_\_\_ (time).

Printed Name of Sheriff or Server

Signature of Sheriff or Server

Subscribed and Sworn To me before this \_\_\_\_\_ (day) \_\_\_\_\_ (month) \_\_\_\_\_ (year)

I am: (check one)

- ☐ the clerk of the court of which affiant is an officer.
- ☐ the judge of the court of which affiant is an officer.
- ☐ authorized to administer oaths in the state in which the affiant served the above summons.  
(use for out-of-state officer)
- ☐ authorized to administer oaths. (use for court-appointed server)

(Seal)

Signature and Title

**Service Fees, if applicable**

Summons \$ \_\_\_\_\_  
Non Est \$ \_\_\_\_\_  
Mileage \$ \_\_\_\_\_ (\_\_\_\_\_ miles @ \$ \_\_\_\_\_ per mile)  
Total \$ \_\_\_\_\_

**EXHIBIT A**

See the following page for directions to clerk and to officer making return on service of summons.

### **Directions to Clerk**

Personal service outside the State of Missouri is permitted only upon certain conditions set forth in Rule 54. The clerk should insert in the summons the names of only the Defendant/Respondent or Defendants/Respondents who are to be personally served by the officer to whom the summons is delivered. The summons should be signed by the clerk or deputy clerk under the seal of the court and a copy of the summons and a copy of the petition for each Defendant/Respondent should be mailed along with the original summons to the officer who is to make service. The copy of the summons may be a carbon or other copy and should be signed and sealed in the same manner as the original but it is unnecessary to certify that the copy is a true copy. The copy of the motion may be a carbon or other copy and should be securely attached to the copy of the summons but need not be certified a true copy. If the Plaintiff's/Petitioner has no attorney, the Plaintiff's/Petitioner's address and telephone number should be stated in the appropriate square on the summons. This form is not for use in attachment actions. (See Rule 54.06, 54.07 and 54.14)

### **Directions to Officer Making Return on Service of Summons**

A copy of the summons and a copy of the motion must be served on each Defendant/Respondent. If any Defendant/Respondent refuses to receive the copy of the summons and motion when offered, the return shall be prepared accordingly so as to show the offer of the officer to deliver the summons and motion and the Defendant's/Respondent's refusal to receive the same.

Service shall be made: (1) On Individual. On an individual, including an infant or incompetent person not having a legally appointed guardian, by delivering a copy of the summons and motion to the individual personally or by leaving a copy of the summons and motion at the individual's dwelling house or usual place of abode with some person of the family over 15 years of age, or by delivering a copy of the summons and petition to an agent authorized by appointment or required by law to receive service of process; (2) On Guardian. On an infant or incompetent person who has a legally appointed guardian, by delivering a copy of the summons and motion to the guardian personally; (3) On Corporation, Partnership or Other Unincorporated Association. On a corporation, partnership or unincorporated association, by delivering a copy of the summons and motion to an officer, partner, or managing or general agent, or by leaving the copies at any business office of the Defendant/Respondent with the person having charge thereof or by delivering copies to its registered agent or to any other agent authorized by appointment or required by law to receive service of process; (4) On Public or Quasi-Public Corporation or Body. Upon a public, municipal, governmental or quasi-public corporation or body in the case of a county, to the mayor or city clerk or city attorney in the case of a city, to the chief executive officer in the case of any public, municipal, governmental, or quasi-public corporation or body or to any person otherwise lawfully so designated.

Service may be made by an officer or deputy authorized by law to serve process in civil actions within the state or territory where such service is made.

Service may be made in any state or territory of the United States. If served in a territory, substitute the word "territory" for the word "state."

The officer making the service must swear an affidavit before the clerk, deputy clerk, or judge of the court of which the person is an officer or other person authorized to administer oaths. This affidavit must state the time, place, and manner of service, the official character of the affiant, and the affiant's authority to serve process in civil actions within the state or territory where service is made.

Service must not be made less than ten days nor more than 30 days from the date the Defendant/Respondent is to appear in court. The return should be made promptly and in any event so that it will reach the Missouri Court within 30 days after service.

**MISSOURI CIRCUIT COURT  
TWENTY-SECOND JUDICIAL CIRCUIT  
ST. LOUIS CITY**

**ALVIN ADLER, Individually,  
and  
KATHLEEN NEWBERRY, Individually,  
and  
LORA HURST, Individually and as  
Representative of the Estate of Sarah  
Loveless, Deceased,  
and  
MICHAEL SILVER, Individually,  
and  
TERESA ANN GRIMES KIDD,  
Individually and as Representative of the  
Estate of Doris Grimes, Deceased,  
and  
RALPH MALONE, Individually,  
and  
RUBY GILLIOM, Individually,  
and  
CYNTHIA MILANAK, Individually and  
as Representative of the Estate of Joseph  
Milanak, Deceased,  
and  
ROSALINE DAVIS, Individually,  
and  
DORIS MOORE, Individually,  
and  
PHYLLIS KVASNICKA, Individually  
and as Representative of the Estate of  
John Kvasnicka, Deceased,  
and  
GAYLE MCCLARD, Individually,  
and**

**Case No.**

**Division:**

**JURY TRIAL DEMANDED**

**ROBERT EUGENE HALL, JR.,**  
**Individually,**  
**and**  
**CONNIE SPEARS, Individually,**  
**and**  
**STEVEN GILLEY, Individually,**  
**and**  
**MARYLEE KEAYS, Individually,**  
**and**  
**LORA LITTLE, Individually,**  
**and**  
**BRUCE TODHUNTER, Individually,**  
**and**  
**PAUL REARICK, Individually and as**  
**Representative of the Estate of Jean**  
**Rearick, Deceased,**  
**and**  
**JOYCE ROMNEY, Individually and as**  
**Representative of the Estate of Roy**  
**Romney, Deceased,**  
**and**  
**NANCY LEIGH SCHMIEDEKE,**  
**Individually,**  
**MARLYNN HEDGECK, Individually,**  
**and**  
**FREDERICK ARCER, Individually,**  
**and**  
**JAMES BEATY, Individually,**  
**and**  
**BARRY BENDER, Individually,**  
**and**  
**VERNON BRICKLEY, Individually,**  
**and**

**CYNTHIA BROWN-MOORE,**  
**Individually and as Representative of the**  
**Estate of Lucy Brown, Deceased,**

**and**

**MARGARET CAMPBELL, Individually,**  
**and**

**THOMAS CRAPS, Individually,**  
**and**

**THOMAS DAVIS, Individually,**  
**and**

**SYLVIA ENGLISH, Individually,**  
**and**

**JAMES FAZZONE, Individually,**  
**and**

**DEANNA HODGES, Individually,**  
**and**

**SANDRA KRAUS, Individually and as**  
**Representative of the Estate of Louise**  
**Davis, Deceased,**

**and**

**ANTHONY LESLIE, Individually,**  
**and**

**MAXINE MATTHEWS, Individually,**  
**and**

**RUTH MCDOWELL, Individually,**  
**and**

**CECILIA MCMURDIE, Individually,**  
**and**

**WANDA MILLS, Individually,**  
**and**

**THEODORE MISNA, Individually,**  
**and**

**WOLFGANG MOLL, Individually,**

and

**JAMES PENNEY, SR., Individually,**

and

**AL DJANGO QUINTOS, Individually,**

and

**HAROLD REDENBAUGH, Individually,**

and

**GAINES SMITH, Individually**

and

**PAUL SMITH, Individually and as  
Representative of the Estate of Genevieve  
Smith, Deceased,**

and

**MARGUERITE SMITH, Individually,**

and

**MARY STAPLES, Individually and as the  
Representative of the Estate of Leslie  
Eugene Staples, Deceased,**

and

**WILLIARD STOCKWELL, Individually,**

and

**MARGARET SWANINGSON,  
Individually,**

and

**CHARLES TILLERY, Individually,**

and

**JOHN VEITH, Individually,**

and

**MARION WEBER, Individually,**

and

**JOE WELLS, Individually,**

and

**CHRISTIAN WILLIAMS, Individually,**

and

**ELIZABETH YAGODA, Individually,**  
**and**  
**GERALD ATKINSON, Individually,**  
**and**  
**CAROL BARGNESI, Individually and as**  
**Representative of the Estate of John**  
**Bargnesi, Deceased,**  
**and**  
**JUANITA HUNTER, Individually,**  
**and**  
**KENNEY JOYCE, Individually,**  
**and**  
**DOLORES KING, Individually,**  
**and**  
**BRUCE LORENC, Individually,**  
**and**  
**WANDA MATLOCK, Individually,**  
**and**  
**DONALD ROLLA, Individually,**  
**and**  
**ARCHEY SEGARS, Individually,**  
**and**  
**DONALD WEEMS, Individually,**  
**and**  
**JOHN BECHTOLD, Individually,**  
**and**  
**LINDA CERASALE, Individually,**  
**and**  
**ELIZABETH CHRISTIAN, Individually,**  
**and**  
**DOMINIC DI EGIDIO, Individually,**  
**and**  
**ESTHER FERGUSON, Individually,**

and  
PATRICIA GURNEY, Individually,  
and  
JAMES HUEBER, Individually,  
and  
WARREN JANKOWSKI, Individually,  
and  
JOSEPH MATERNA, Individually,  
and  
RONALD NAPT, Individually,  
and  
WILLIE REMO, Individually,  
and  
RONALD REYNOLDS, Individually,  
and  
RICHARD SHERRETTA, SR.,  
Individually,  
and  
DORIS STARR, Individually,  
and  
EARLE STUBBERT, Individually,  
and  
ROBERT SWARTZMILLER,  
Individually,  
and  
GILBERT THOMPSON, Individually,  
and  
SHAMAR BEASLEY, Individually,  
and  
EILEEN NEIBAUER, Individually,  
and  
DEBRA VAUGHT, Individually,  
and



**WILLIAM WHITE, Individually,  
and  
WILLIAM MCCLELLAN, Individually,  
and  
SHIRLEY LARSON, Individually,**

**Plaintiffs**

**v.**

**BOEHERINGER INGELHEIM  
PHARMACEUTICALS INC., and  
Serve: Registered Agent  
CT Corporation System  
221 Bolivar Street  
Jefferson City, Missouri 65101**

**BOEHERINGER INGELHEIM  
INTERNATIONAL GMBH,  
Serve: Principal Place of Business  
Binger Strasse 173  
55216 Ingelheim am Rhein  
Germany**

**Defendants.**

**PETITION**

**COME NOW** the Plaintiffs, Alvin Adler, Individually; Kathleen Newberry, Individually; Lora Hurst, Individually and as Representative of the Estate of Sarah Loveless, Deceased; Michael Silver, Individually; Teresa Ann Grimes Kidd, Individually and as Representative of the Estate of Doris Grimes, Deceased; Ralph Malone, Individually; Ruby Gilliom, Individually; Cynthia Milanak, Individually and as Representative of the Estate of Joseph Milanak, Deceased; Rosaline Davis, Individually; Doris Moore, Individually; Phyllis Kvasnicka, Individually and as Representative of the Estate of John Kvasnicka, Deceased; Gayle McClard, Individually; Robert Eugene Hall, Jr., Individually; Connie Spears, Individually; Steven Gilley, Individually; Marylee Keays, Individually; Lora Little, Individually; Bruce Todhunter, Individually; Paul Rearick,

Individually and as Representative of the Estate of Jean Rearick, Deceased; Joyce Romey, Individually and as Representative of the Estate of Roy Romey, Deceased; Nancy Leigh Schmiedeke, Individually; Marlynn Hedgecock, Individually; Frederick Archer, Individually; James Beaty, Individually; Barry Bender, Individually; Vernon Brickley, Individually; Cynthia Brown-Moore, Individually and as Representative of the Estate of Lucy Brown, Deceased; Margaret Campbell, Individually; Thomas Craps, Individually; Thomas Davis, Individually; Sylvia English, Individually; James Fazzone, Individually; Deanna Hodges, Individually; Sandra Kraus, Individually and as Representative of the Estate of Louise Davis, Deceased; Anthony Leslie, Individually; Maxine Matthews, Individually; Ruth McDowell, Individually; Cecelia McMurdie, Individually; Wanda Mills, Individually; Theodore Misna, Individually; Wolfgang Moll, Individually; James Penney, Sr.; Individually; Al Django Quintos, Individually; Harold Redenbaugh, Individually; Gaines Smith, Individually; Paul Smith, Individually and as Representative of the Estate of Genevieve Smith, Deceased; Marguerite Smith, Individually; Mary Staples, Individually and as Representative of the Estate of Leslie Eugene Staples, Deceased; Willard Stockwell, Individually; Margaret Swaningson, Individually; Charles Tillery, Individually; John Veith, Individually; Marion Weber, Individually; Joe Wells, Individually; Christian Williams, Individually; Elizabeth Yagoda, Individually; Gerald Adkinson, Individually; Carol Bargnesi, Individually and as Representative of the Estate of John Bargnesi, Deceased; Juanita Hunter, Individually; Kenney Joyce, Individually; Dolores King, Individually; Bruce Lorenc, Individually; Wanda Matlock, Individually; Donald Rolla, Individually; Archey Segars, Individually; Douglas Weems, Individually; John Bechtold, Individually; Linda Cerasale, Individually; Elizabeth Christian, Individually; Dominic Di Egidio, Individually; Esther Ferguson, Individually; Patricia Gurney, Individually; James Hueber, Individually; Warren Jankowski,

Individually; Joseph Materna, Individually; Ronald Napty, Individually; Willie Remo, Individually; Ronald Reynolds, Individually; Richard Sherretta, Sr., Individually; Doris Starr, Individually; Earle Stubbart, Individually; Robert Swartzmiller, Individually; Gilbert Thompson, Individually; Shamar Beasley, Individually; Eileen Neibauer, Individually; Debra Vaught, Individually; William White, Individually; William McClellan, Individually; Shirley Larson, Individually; by and through their undersigned attorneys, and hereby bring this action against the Defendants, Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH, as follows:

### **NATURE OF THE ACTION**

1. Pradaxa® (dabigatran etexilate) is an oral anticoagulant, approved by the FDA in October 2010 as a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in adults with non-valvular atrial.
2. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold Pradaxa® as an oral anticoagulation medication indicated to reduce the risk of stroke and systemic embolism in adults with non-valvular atrial fibrillation.
3. The Defendants' marketing and informational materials represented that atrial fibrillation is the most common heart rhythm condition in the world, with one in four (4) adults over the age of 40 developing the condition in their life time.
4. Atrial fibrillation is a type of irregular heartbeat that occurs when one or both of the upper chambers of the heart, called the atria, function in an erratic manner.
5. The evidence will establish that even though atrial fibrillation is not a life-threatening condition, it can in certain circumstances have serious and/or fatal consequences.

6. The evidence will establish, and Defendants agree, that clotting in patients with atrial fibrillation occurs more frequently than in the general population. If left untreated according to Defendants, patients with atrial fibrillation have a five-fold (5) increased risk of stroke when compared to people without atrial fibrillation. Up to three (3) million people worldwide suffer strokes related to atrial fibrillation each year. Strokes due to atrial fibrillation tend to be severe, with an increased likelihood of death and disability.
7. Pradaxa® is claimed by Defendants to be the solution to the clotting problem in adults with atrial fibrillation. Specifically, Defendants claim that many atrial fibrillation-related strokes can be prevented with appropriate medicinal therapy. For this, substances are used which act on the blood clotting system and shall prevent blood clots from forming.
8. Before Pradaxa®, atrial fibrillation patients have been treated with Coumadin, a well-known oral anticoagulant that has been on the market for over 50 years. While there are certain problems associated with the use of Coumadin, many of the side effects can be addressed through monitoring and the administration of Vitamin K to minimize any problems associated with bleeding. Such is not the case with Pradaxa®, which was intensely promoted to doctors as a drug that does not require regular monitoring.
9. Pradaxa® is an oral anticoagulant and is a direct thrombin inhibitor, also known as DTI.
10. Pradaxa® is not safer than Coumadin. While offering some level of convenience, from a safety perspective as compared to Coumadin, its risks greatly exceed any such convenience, which was the basic component in Defendants' marketing launch.
11. The evidence will establish that Pradaxa® sales increased rapidly after its launch in 2010, as did the FDA Serious Adverse Event Reports associated with its use.

12. Pradaxa®, because of its marketing and design defects, puts patients at an increased risk for developing life threatening bleeds.
13. The evidence will establish that by November of 2010, there were at least 260 fatal bleeding events reported in patients taking Pradaxa®. At the time of the filing of this complaint, Pradaxa has the number one cause of adverse events reported to the FDA.
14. As a result of Defendants' actions, Plaintiffs and their physicians were unaware and could not have reasonably known or learned through reasonable diligence, that Plaintiffs would be exposed to the risks identified in this Complaint. The increased risks and subsequent medical damages associated with Plaintiffs' Pradaxa® use were the direct and proximate result of Defendants' conduct.

### **PARTIES**

#### **PLAINTIFFS:**

15. Plaintiff Alvin Adler is a natural person. At all times relevant hereto, Plaintiff Alvin Adler was and is a resident and citizen of the State of New York.
16. Plaintiff Kathleen Newberry is a natural person. At all times relevant hereto, Plaintiff Kathleen Newberry was and is a resident and citizen of the State of Missouri.
17. Plaintiff Lora Hurst is the daughter of Sarah Loveless, deceased, and the Representative of the Estate of Sarah Loveless, deceased, and brings this action for individual claims, including the claims for the wrongful death of Sarah Loveless and the claims of the estate. At all times relevant hereto, Plaintiff Lora Hurst and Decedent Sarah Loveless were residents and citizens of the State of Missouri.
18. Plaintiff Michael Silver is a natural person. At all times relevant hereto, Plaintiff Michael Silver was and is a resident and citizen of the State of Maryland.

19. Plaintiff Teresa Ann Grimes Kidd is the daughter of Doris Grimes, deceased, and the Representative of the Estate of Doris Grimes, deceased, and brings this action for individual claims, including the claims for the wrongful death of Doris Grimes and the claims of the estate. At all times relevant hereto, Plaintiff Teresa Ann Grimes Kidd and Decedent Doris Grimes were residents and citizens of the State of Tennessee.
20. Plaintiff Ralph Malone is a natural person. At all times relevant hereto, Plaintiff Ralph Malone was and is a resident and citizen of the State of South Carolina.
21. Plaintiff Ruby Gilliom is a natural person. At all times relevant hereto, Plaintiff Ruby Gilliom was and is a resident and citizen of the State of Indiana.
22. Plaintiff Cynthia Milanak is the surviving spouse of Joseph Milanak, deceased, and the Representative of the Estate of Joseph Milanak, deceased, and brings this action for individual claims, including the claims for the wrongful death of Joseph Milanak and the claims of the estate. At all times relevant hereto, Plaintiff Cynthia Milanak and Decedent Joseph Milanak were residents and citizens of the State of Pennsylvania.
23. Plaintiff Rosaline Davis is a natural person. At all times relevant hereto, Plaintiff Rosaline Davis was and is a resident and citizen of the State of Louisiana.
24. Plaintiff Doris Moore is a natural person. At all times relevant hereto, Plaintiff Doris Moore was and is a resident and citizen of the State of California.
25. Plaintiff Phyllis Kvasnicka is the surviving spouse of John Kvasnicka, deceased, and the Representative of the Estate of John Kvasnicka, deceased, and brings this action for individual claims, including the claims for the wrongful death of John Kvasnicka and the claims of the estate. At all times relevant hereto, Plaintiff Phyllis Kvasnicka and Decedent John Kvasnicka were residents and citizens of the State of Virginia.

26. Plaintiff Gayle McClard is a natural person. At all times relevant hereto, Plaintiff Gayle McClard was and is a resident and citizen of the State of Kentucky.
27. Plaintiff Robert Eugene Hall, Jr. is a natural person. At all times relevant hereto, Plaintiff Robert Eugene Hall, Jr. was and is a resident and citizen of the State of Ohio.
28. Plaintiff Connie Spears is a natural person. At all times relevant hereto, Plaintiff Connie Spears was and is a resident and citizen of the State of Ohio.
29. Plaintiff Steven Gilley is a natural person. At all times relevant hereto, Plaintiff Steven Gilley was and is a resident and citizen of the State of Colorado.
30. Plaintiff Marylee Keays is a natural person. At all times relevant hereto, Plaintiff Marylee Keays was and is a resident and citizen of the State of Indiana.
31. Plaintiff Lora Little is a natural person. At all times relevant hereto, Plaintiff Lora Little was and is a resident and citizen of the State of Washington.
32. Plaintiff Bruce Todhunter is a natural person. At all times relevant hereto, Plaintiff Bruce Todhunter was and is a resident and citizen of the State of Missouri.
33. Plaintiff Paul Rearick is the son of Jean Rearick, deceased, and the Representative of the Estate of Jean Rearick, deceased, and brings this action for individual claims, including the claims for the wrongful death of Jean Rearick and the claims of the estate. At all times relevant hereto, Plaintiff Paul Rearick and Decedent Jean Rearick were residents and citizens of the State of Pennsylvania.
34. Plaintiff Joyce Romey is the surviving spouse of Roy Romey, deceased, and the Representative of the Estate of Roy Romey, deceased, and brings this action for individual claims, including the claims for the wrongful death of Roy Romey and the

claims of the estate. At all times relevant hereto, Plaintiff Joyce Romey and Decedent Roy Romey were residents and citizens of the State of Washington.

35. Plaintiff Nancy Leigh Schmiedeke is a natural person. At all times relevant hereto, Plaintiff Nancy Leigh Schmiedeke was and is a resident and citizen of St. Louis, Missouri.

36. Plaintiff Marlynn Hedgecock is a natural person. At all times relevant hereto, Plaintiff Marlynn Hedgecock was and is a resident and citizen of the State of Delaware.

37. Plaintiff Frederick Archer is a natural person. At all times relevant hereto, Plaintiff Frederick Archer was and is a resident and citizen of the State of Maryland.

38. Plaintiff James Beaty is a natural person. At all times relevant hereto, Plaintiff James Beaty was and is a resident and citizen of the State of Tennessee.

39. Plaintiff Barry Bender is a natural person. At all times relevant hereto, Plaintiff Barry Bender was and is a resident and citizen of the State of Pennsylvania.

40. Plaintiff Vernon Brickley is a natural person. At all times relevant hereto, Plaintiff Vernon Brickley was and is a resident and citizen of the State of Illinois.

41. Plaintiff Cynthia Brown-Moore is the daughter of Lucy Brown, deceased, and the Representative of the Estate of Lucy Brown, deceased, and brings this action for individual claims, including the claims for the wrongful death of Lucy Brown and the claims of the estate. At all times relevant hereto, Plaintiff Cynthia Brown-Moore and Decedent Lucy Brown were residents and citizens of the State of Massachusetts.

42. Plaintiff Margaret Campbell is a natural person. At all times relevant hereto, Plaintiff Margaret Campbell was and is a resident and citizen of the State of Oregon.

43. Plaintiff Thomas Craps is a natural person. At all times relevant hereto, Plaintiff Thomas Craps was and is a resident and citizen of the State of South Carolina.



44. Plaintiff Thomas Davis is a natural person. At all times relevant hereto, Plaintiff Thomas Davis was and is a resident and citizen of the State of Montana.
45. Plaintiff Sylvia English is a natural person. At all times relevant hereto, Plaintiff Sylvia English was and is a resident and citizen of the State of Georgia.
46. Plaintiff James Fazzone is a natural person. At all times relevant hereto, Plaintiff James Fazzone was and is a resident and citizen of the State of New Jersey.
47. Plaintiff Deanna Hodges is a natural person. At all times relevant hereto, Plaintiff Deanna Hodges was and is a resident and citizen of the State of North Carolina.
48. Plaintiff Sandra Kraus is the daughter of Louise Davis, deceased, and the Representative of the Estate of Louise Davis, deceased, and brings this action for individual claims, including the claims for the wrongful death of Louise Davis and the claims of the estate. At all times relevant hereto, Plaintiff Sandra Kraus and Decedent Louise Davis were residents and citizens of the State of Kansas.
49. Plaintiff Anthony Leslie is a natural person. At all times relevant hereto, Plaintiff Anthony Leslie was and is a resident and citizen of the State of Alabama.
50. Plaintiff Maxine Matthews is a natural person. At all times relevant hereto, Plaintiff Maxine Matthews was and is a resident and citizen of the State of Alabama.
51. Plaintiff Ruth McDowell is a natural person. At all times relevant hereto, Plaintiff Ruth McDowell was and is a resident and citizen of the State of Pennsylvania.
52. Plaintiff Cecelia McMurdie is a natural person. At all times relevant hereto, Plaintiff Cecelia McMurdie was and is a resident and citizen of the State of Arizona.
53. Plaintiff Wanda Mills is a natural person. At all times relevant hereto, Plaintiff Wanda Mills was and is a resident and citizen of the State of Florida.

54. Plaintiff Theodore Misna is a natural person. At all times relevant hereto, Plaintiff Theodore Misna was and is a resident and citizen of the State of Illinois.
55. Plaintiff Wolfgang Moll is a natural person. At all times relevant hereto, Plaintiff Wolfgang Moll was and is a resident and citizen of the State of Florida
56. Plaintiff James Penney, Sr. is a natural person. At all times relevant hereto, Plaintiff James Penney, Sr. was and is a resident and citizen of the State of Alabama.
57. Plaintiff Al Django Quintos is a natural person. At all times relevant hereto, Plaintiff Al Django Quintos was and is a resident and citizen of the State of Nevada.
58. Plaintiff Harold Redenbaugh is a natural person. At all times relevant hereto, Plaintiff Harold Redenbaugh was and is a resident and citizen of the State of Iowa.
59. Plaintiff Gaines Smith is a natural person. At all times relevant hereto, Plaintiff Gaines Smith was and is a resident and citizen of the State of Missouri.
60. Plaintiff Paul Smith is the surviving spouse of Genevieve Smith, deceased, and the Representative of the Estate of Genevieve Smith, deceased, and brings this action for individual claims, including the claims for the wrongful death of Genevieve Smith and the claims of the estate. At all times relevant hereto, Plaintiff Paul Smith and Decedent Genevieve Smith were residents and citizens of the State of Connecticut.
61. Plaintiff Marguerite Smith is a natural person. At all times relevant hereto, Plaintiff Marguerite Smith was and is a resident and citizen of the State of Alabama.
62. Plaintiff Mary Staples is the surviving spouse of Leslie Eugene Staples, deceased, and the Representative of the Estate of Leslie Eugene Staples, deceased, and brings this action for individual claims, including the claims for the wrongful death of Leslie Eugene

Staples and the claims of the estate. At all times relevant hereto, Plaintiff Mary Staples and Decedent Leslie Eugene Staples were residents and citizens of the State of Arkansas.

63. Plaintiff Willard Stockwell is a natural person. At all times relevant hereto, Plaintiff Willard Stockwell was and is a resident and citizen of the State of Arkansas.

64. Plaintiff Margaret Swaningson is a natural person. At all times relevant hereto, Plaintiff Margaret Swaningson was and is a resident and citizen of the State of Wisconsin.

65. Plaintiff Charles Tillery is a natural person. At all times relevant hereto, Plaintiff Charles Tillery was and is a resident and citizen of the State of Texas.

66. Plaintiff John Veith is a natural person. At all times relevant hereto, Plaintiff John Veith was and is a resident and citizen of the State of Ohio.

67. Plaintiff Marion Weber is a natural person. At all times relevant hereto, Plaintiff Marion Weber was and is a resident and citizen of the State of New Jersey.

68. Plaintiff Joe Wells is a natural person. At all times relevant hereto, Plaintiff Joe Wells was and is a resident and citizen of the State of Texas.

69. Plaintiff Christian Williams is a natural person. At all times relevant hereto, Plaintiff Christian Williams was and is a resident and citizen of the State of Virginia.

70. Plaintiff Elizabeth Yagoda is a natural person. At all times relevant hereto, Plaintiff Elizabeth Yagoda was and is a resident and citizen of the State of Minnesota.

71. Plaintiff Gerald Adkinson is a natural person. At all times relevant hereto, Plaintiff Gerald Adkinson was and is a resident and citizen of the State of Florida.

72. Plaintiff Carol Bargnesi is the surviving spouse of John Bargnesi, deceased, and the Representative of the Estate of John Bargnesi, deceased, and brings this action for individual claims, including the claims for the wrongful death of John Bargnesi and the

claims of the estate. At all times relevant hereto, Plaintiff Carol Bargnesi and Decedent John Bargnesi were residents and citizens of the State of New York.

73. Plaintiff Juanita Hunter is a natural person. At all times relevant hereto, Plaintiff Juanita Hunter was and is a resident and citizen of the State of Florida.

74. Plaintiff Kenney Joyce is a natural person. At all times relevant hereto, Plaintiff Kenny Joyce was and is a resident and citizen of the State of West Virginia.

75. Plaintiff Dolores King is a natural person. At all times relevant hereto, Plaintiff Dolores King was and is a resident and citizen of the State of Illinois.

76. Plaintiff Bruce Lorenc is a natural person. At all times relevant hereto, Plaintiff Bruce Lorenc was and is a resident and citizen of the State of North Carolina.

77. Plaintiff Wanda Matlock is a natural person. At all times relevant hereto, Plaintiff Wanda Matlock was and is a resident and citizen of the State of Louisiana.

78. Plaintiff Donald Rolla is a natural person. At all times relevant hereto, Plaintiff Donald Rolla was and is a resident and citizen of the State of Illinois.

79. Plaintiff Archey Segars is a natural person. At all times relevant hereto, Plaintiff Archey Segars was and is a resident and citizen of the State of Georgia.

80. Plaintiff Douglas Weems is a natural person. At all times relevant hereto, Plaintiff Douglas Weems was and is a resident and citizen of the State of Alabama.

81. Plaintiff John Bechtold is a natural person. At all times relevant hereto, Plaintiff John Bechtold was and is a resident and citizen of the State of Florida.

82. Plaintiff Linda Cerasale is a natural person. At all times relevant hereto, Plaintiff Linda Cerasale was and is a resident and citizen of the State of Arkansas.

83. Plaintiff Elizabeth Christian is a natural person. At all times relevant hereto, Plaintiff Elizabeth Christian was and is a resident and citizen of the State of Missouri.
84. Plaintiff Dominic Di Egidio is a natural person. At all times relevant hereto, Plaintiff Dominic Di Egidio was and is a resident and citizen of the State of Pennsylvania.
85. Plaintiff Esther Ferguson is a natural person. At all times relevant hereto, Plaintiff Esther Ferguson was and is a resident and citizen of the State of Florida.
86. Plaintiff Patricia Gurney is a natural person. At all times relevant hereto, Plaintiff Patricia Gurney was and is a resident and citizen of the State of New York.
87. Plaintiff James Hueber is a natural person. At all times relevant hereto, Plaintiff James Hueber was and is a resident and citizen of the State of Virginia.
88. Plaintiff Warren Jankowski is a natural person. At all times relevant hereto, Plaintiff Warren Jankowski was and is a resident and citizen of the State of Pennsylvania.
89. Plaintiff Joseph Materna is a natural person. At all times relevant hereto, Plaintiff Joseph Materna was and is a resident and citizen of the State of Pennsylvania.
90. Plaintiff Ronald Napy is a natural person. At all times relevant hereto, Plaintiff Ronald Napy was and is a resident and citizen of the State of Georgia.
91. Plaintiff Willie Remo is a natural person. At all times relevant hereto, Plaintiff Willie Remo was and is a resident and citizen of the State of Louisiana.
92. Plaintiff Ronald Reynolds is a natural person. At all times relevant hereto, Plaintiff Ronald Reynolds was and is a resident and citizen of the State of Iowa.
93. Plaintiff Richard Sherretta, Sr. is a natural person. At all times relevant hereto, Plaintiff Richard Sherretta, Sr. was and is a resident and citizen of the State of New Jersey.

94. Plaintiff Doris Starr is a natural person. At all times relevant hereto, Plaintiff Doris Starr was and is a resident and citizen of the State of Oklahoma.
95. Plaintiff Earle Stubbert is a natural person. At all times relevant hereto, Plaintiff Earle Stubbert was and is a resident and citizen of the State of California.
96. Plaintiff Robert Swartzmiller is a natural person. At all times relevant hereto, Plaintiff Robert Swartzmiller was and is a resident and citizen of the State of West Virginia.
97. Plaintiff Gilbert Thompson is a natural person. At all times relevant hereto, Plaintiff Gilbert Thompson was and is a resident and citizen of the State of Georgia.
98. Plaintiff Shamar Beasley is a natural person. At all times relevant hereto, Plaintiff Shamar Beasley was and is a resident and citizen of the State of Louisiana.
99. Plaintiff Eileen Neibauer is a natural person. At all times relevant hereto, Plaintiff Eileen Neibauer was and is a resident and citizen of the State of Pennsylvania.
100. Plaintiff Debra Vaught is a natural person. At all times relevant hereto, Plaintiff Debra Vaught was and is a resident and citizen of the State of Ohio.
101. Plaintiff William White is a natural person. At all times relevant hereto, Plaintiff William White was and is a resident and citizen of the State of Virginia.
102. Plaintiff William McClellan is a natural person. At all times relevant hereto, Plaintiff William McClellan was and is a resident and citizen of the State of Arizona.
103. Plaintiff Shirley Larson is a natural person. At all times relevant hereto, Plaintiff Shirley Larson was and is a resident and citizen of the State of California.
104. As a direct result of being prescribed Pradaxa®, Plaintiffs suffered severe mental anguish, as well as physical pain and suffering as a result of their exposure to Pradaxa®.

**DEFENDANTS:**

105. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a Delaware Corporation which has its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. BIPI may be served at CT Corporation System, 221 Bolivar Street, Jefferson City, Missouri 65101. BIPI has conducted business and derived substantial revenue from within the State of Missouri.
106. Defendant Boehringer Ingelheim International GmbH (“BII”) is a German corporation, with its worldwide corporate headquarters located at Binger Str. 173, 55216 Ingelheim, Germany. BII is the corporate parent of Defendant BIPI, and may be served through the Hague Convention. BII has conducted business and derived substantial revenue from within the State of Missouri.
107. Defendant BIPI and Defendant BII may be referred to collectively in this Complaint as “Boehringer”.

**JURISDICTION AND VENUE**

108. There is no federal subject matter jurisdiction because no federal question is raised. Additionally, Defendant BIPI is incorporated in the State of Delaware, the same state of which Plaintiff Marlynn Hedgecock is a citizen, and has its principal places of business in Connecticut, the same state of which Plaintiff Paul Smith is a citizen. As such, there is a lack of complete diversity among the parties. Moreover, Plaintiffs’ Petition does not constitute a “mass action” under 28 U.S.C. § 1332(d)(11)(B)(i) because there are fewer than 100 Plaintiffs named herein, and Plaintiffs explicitly deny and disclaim any intent or proposal under which Plaintiffs’ claims would be tried jointly with those of any other Plaintiffs. Plaintiffs herein further explicitly deny and disclaim any intent or proposal to

join or consolidate the claims of the Plaintiffs herein with the claims of any other Plaintiffs who might have brought or may bring in the future any claims against these Defendants arising out of Pradaxa® use and injuries caused thereby.

109. Jurisdiction is proper here in that Defendants do business in the State of Missouri and committed torts in whole or in part against Plaintiffs in Missouri. Defendants marketed, promoted and sold Pradaxa® throughout the United States, including the City of St. Louis, Missouri.
110. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has in personam jurisdiction over Defendants because Defendants transact substantial and continuous business in Missouri, and has a registered agent within the state of Missouri. Defendants are present in the State of Missouri such that requiring an appearance does not offend traditional notions of fair play and substantial justice.
111. Plaintiffs are informed and believe that, at all times material to this action, Defendants and/or one of their wholly owned divisions engaged in business in the State of Missouri. Defendants directly or indirectly, negligently and/or defectively made, created, designed, developed, manufactured, assembled, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold in interstate commerce, in the State of Missouri, its prescription drug Pradaxa®. Defendants reasonably expected that Pradaxa® would be sold and consumed in the State of Missouri. Because Defendants regularly conducted business in the State of Missouri, received substantial revenues from the State of Missouri and/or distributed products in the State of Missouri, Defendants are subject to suit in the State of Missouri.



112. This Court has personal jurisdiction over Defendants pursuant to and consistent with RSMo. §§ 407.025, 506.500, and the Constitutional requirements of Due Process in that Defendants, acting through their apparent agents, committed one or more of the following acts:
- a. Defendants transacted business in the State of Missouri. RSMo. § 506.500.1(1);
  - b. Defendants made or performed a contract or promise substantially connected with/or within the State of Missouri. RSMo. § 506.500.1(2);
  - c. Defendants committed and conspired to commit a tortious act within the State of Missouri. RSMo. § 506.500.1(3);
  - d. Defendants owned, used or possessed real estate situated in the State of Missouri. RSMo. § 506.500.1(4);
  - e. At all relevant times, it was foreseeable to Defendants that their tortious acts and/or their transaction of business in the State of Missouri would have consequences such that Defendants could reasonably foresee being hailed into Court in the State of Missouri;
  - f. Requiring Defendants to litigate this claim in Missouri does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.
113. Venue is proper in this Court pursuant to Mo. Rev. Stat § 508.010.5(1) because Plaintiff Nancy Leigh Schmiedeke's principal place of residence was in the county of St. Louis City, Missouri, on the date she was first injured, and she was injured outside the state of Missouri in the state of Florida where she was hospitalized for a gastrointestinal bleed.
114. The claims in this case present common questions of fact and law concerning, among other things, what information Defendants possessed concerning the harmful effects of Pradaxa®, what information they disclosed to physicians and patients about those harmful effects, and what information Defendants were required by law to disclose about those effects. Plaintiffs herein are properly joined pursuant to the Missouri rule on

permissive joinder, Missouri Rule of Civil Procedure 52.05(a). Plaintiffs' claims are logically related in that all Plaintiffs claim that Pradaxa® was defectively designed, manufactured and marketed by Defendants and that Defendants failed to provide appropriate warnings and instructions regarding the dangers posed by Pradaxa®. All Plaintiffs suffered similar injuries as a result of using Pradaxa®. Defendants' wrongful conduct, which resulted in Plaintiffs' injuries, is common to all Plaintiffs and includes, but is not limited to, Defendants' failure to conduct adequate safety and efficacy studies, Defendants' submissions to the United States Food and Drug Administration ("FDA"), Defendants' marketing materials and literature distributed to physicians and patients, and the lack of adequate warnings provided to physicians and patients. Defendants' conduct in designing, developing, marketing, and distributing Pradaxa® relates to all Plaintiffs herein and makes up a common universe of facts underlying Plaintiffs' claims, such that Plaintiffs' claims against Defendants arise from the same transaction or occurrence or the same series of transactions or occurrences. Because Plaintiff Nancy Leigh Schmiedeke's principal place of residence was in the county of St. Louis City, Missouri, on the date she was first injured, and her claims are properly joined with all other Plaintiffs' claims, venue is proper for all Plaintiffs.

#### **TOLLING OF APPLICABLE STATUTE OF LIMITATIONS**

115. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from the Plaintiffs, the public, and prescribing physicians the true risks associated with taking Pradaxa®.
116. As a result of the Defendants' actions, the Plaintiffs and Plaintiffs' prescribing

physicians were unaware, and could not reasonably have known or have learned through reasonable diligence, that the Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendant's acts and omission.

**CLAIMS FOR RELIEF**

**COUNT I**  
**STRICT LIABILITY - FAILURE TO WARN**

117. Plaintiffs incorporate by reference all preceding paragraphs and all of the factual allegations contained therein.
118. Defendants are liable under the theory of strict products liability in that the Defendants were at all times relevant to this action engaged in the business of designing, manufacturing, testing, marketing, and placing into the stream of commerce pharmaceuticals such as Pradaxa® for sale to, and use by, members of the public. The evidence will establish the Pradaxa® manufactured by Defendants was defectively designed and marketed and the defects which caused Plaintiffs' injuries and/or deaths death existed at the time the drug was released into the stream of commerce by these Defendants.
119. The evidence will establish that Defendants knew or should have known the warnings and other information distributed with regard to the use of Pradaxa® were inadequate in at least the following ways:
  - a. Defendants failed to warn that Pradaxa® results in a higher rate of gastrointestinal bleeds than other oral anticoagulants, and that the ingestion of Pradaxa® results in a higher rate of life threatening bleeds than the strokes and systemic embolisms Pradaxa® is intended to prevent.

- b. Prior to 2012, Defendants failed to warn that Pradaxa®-induced bleeds are irreversible and that there is no available reversal agent in the “*Warnings and Precautions*” section of the product label. Until January 2012, the language noting that the bleeds are irreversible and that there is no available reversal agent was buried in obscure, confusing, and inadequate wording located in the “*Overdosage*” portion of the product label.
- c. Despite moving the above information to the “*Warnings and Precautions*” section of the product label in January 2012, Defendants failed at all times to inform physicians that they actually had developed a reversal agent for Pradaxa®-induced bleeds prior to the time Pradaxa® was approved for sale in the United States, but that they failed to seek approval of said reversal agent from the FDA until February 19, 2015, the date on which Defendants submitted their Pradaxa® reversal agent to the FDA for “Accelerated Approval” as provided by 21 CFR 601.41. The FDA approved Defendants’ reversal agent, called Praxbind®, on October 16, 2015, less than eight (8) months after Defendants submitted it for FDA approval.
- d. Defendants failed to warn that there is no accurate test to monitor the level of Pradaxa® in a patient’s blood despite the fact that Pradaxa® has a narrow therapeutic window and is only effective if dosed properly for each individual patient. If the patient has too high a dose of Pradaxa they are at increased risk of suffering a life-threatening bleed, and if the patient has too low a dose of Pradaxa they are at increased risk of suffering a thromboembolic injury.
- e. Defendants failed to warn physicians that there are a group of individuals known as “super absorbers” who, because they suffer some degree of renal insufficiency

and for other unknown reasons, cannot eliminate Pradaxa® from their body at the same rate as non-super absorbers. Defendants are aware that approximately ten percent of those individuals to whom Pradaxa® is prescribed are “super absorbers.” Notwithstanding the knowledge of their existence of that condition, and their knowledge of the serious and sometimes fatal risks associated with that condition, Defendants at all times have marketed Pradaxa® to all patients with no warning whatsoever regarding the fact that ten percent of patients who take Pradaxa® are exposed to a much greater risk of uncontrolled bleeding than other individuals.

120. As a result of Defendants failure to warn physicians of the above, neither Plaintiffs nor their physicians received adequate warnings relative to the risks associated with the use of Pradaxa®. Plaintiffs’ physicians would not have prescribed Pradaxa® had they been aware of the risks associated with the drug, and Plaintiffs would not have ingested Pradaxa® had they been aware of these risks. The evidence will establish that such defects were a producing and/or proximate cause of Plaintiffs’ injuries and/or deaths.
121. Defendants knew or should have known that consumers such as Plaintiffs would needlessly suffer injury and/or death as a result of Defendants’ failures.
122. The evidence will establish that these Defendants failed, throughout the time Pradaxa® has been on the market, to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiffs and their intermediary physicians, regarding the true risks associated with the use of Pradaxa®.

**COUNT II**  
**STRICT LIABILITY**  
**DESIGN DEFECT, MARKETING DEFECT**  
**& CONSTRUCTION OR COMPOSITION DEFECT**

123. Plaintiffs hereby incorporate by reference all preceding paragraphs and all factual allegations contained therein.
124. Pradaxa® was unreasonably defective in design and marketing, considering the utility of the product and the risk involved in its use. As designed and marketed, the risks of bleeding associated with the use of Pradaxa® greatly outweighed its benefits, if any.
125. Pradaxa® is defective in design or formulation for a myriad of reasons including, but not limited to:
- a. It causes a higher rate of life threatening bleeds than the strokes or systemic embolisms it is intended to prevent;
  - b. Its harmful effects cannot be minimized through the administration of Vitamin K or any other antidote<sup>1</sup>;
  - c. It leads to a higher rate of major gastrointestinal bleeds as compared to other oral anticoagulants on the market;
  - d. It does not provide for patient-specific dosing, despite Defendants' knowledge that patients eliminate Pradaxa® from their bodies at different rates, and their knowledge that approximately ten percent of patients are "super absorbers" who eliminate Pradaxa® from their bodies slower than other patients;
  - e. There is no accurate test to monitor the level of Pradaxa® in a patient's blood despite the fact that Pradaxa® has a narrow therapeutic window and is only effective if dosed properly for each individual patient; and
  - f. Despite having actually had developed a reversal agent for Pradaxa®-induced bleeds prior to the time Pradaxa® was approved for sale in the United States, Defendants failed to seek approval of said reversal agent from the FDA until February 19, 2015, the date on which Defendants submitted their Pradaxa® reversal agent to the FDA for "Accelerated Approval" as provided by 21 CFR 601.41.

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<sup>1</sup> Plaintiffs note that Defendants' reversal agent, Praxbind®, was approved on October 16, 2015, which was well after the dates on which Plaintiffs suffered their Pradaxa®-induced bleeds.

g. Pradaxa was not accompanied by adequate warnings and information regarding its very real dangers.

126. For the reasons described above, Pradaxa® was defective in design or formulation in that when it was placed in the stream of commerce by Defendants, it was unreasonably dangerous to an extent beyond that which could reasonably be contemplated by Plaintiffs or their physicians. The evidence will establish that any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used in the manner intended by Defendants herein.

127. The evidence will establish that the defective and unreasonably dangerous design and marketing of Pradaxa® was a direct, proximate and producing cause of Plaintiffs' injuries and/or deaths and related damages. Plaintiffs suffered gastrointestinal or other internal bleeding as a direct result of their ingestion of Pradaxa® - a medication promoted by Defendants as reducing his/her risk of suffering a life threatening stroke or embolism. Pursuant to the provisions of the Restatement (Second) of Torts, Defendants are liable to Plaintiff for all damages claimed in this case, including punitive damages.

### **COUNT III** **NEGLIGENCE**

128. Plaintiffs hereby incorporate by reference all preceding paragraphs and all factual allegations contained therein.

129. Defendants owed a duty to Plaintiffs to exercise reasonable care in the design, development, manufacture, promotion, sale, marketing and distribution of Pradaxa®. Defendants breached that duty since Pradaxa®, as designed, is capable of causing serious personal injuries and death. Defendants also failed to exercise reasonable care in the

marketing of Pradaxa® in that they failed to warn that Pradaxa®, as designed, was capable of causing serious personal injuries and death.

130. Defendants breached their duty and were negligent by, but not limited to, the following actions, misrepresentations, and omissions toward Plaintiffs:

- a. Failing to use due care in developing, testing, designing and manufacturing Pradaxa®.
- b. Failing to accompany their product with proper, adequate warnings and labeling regarding adverse side effects and health risks associated with the use of Pradaxa®.
- c. In providing information to Plaintiffs' physicians that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to patients such as Plaintiffs.
- d. Failing to provide warnings and other information that accurately reflected the symptoms, scope and severity of the side effects and health risks, such as Pradaxa®-induced bleed.
- e. Failing to conduct such testing and post-marketing surveillance as would have been conducted by reasonable and prudent drug manufacturer acting under the same or similar circumstances.
- f. Failing to remove Pradaxa® from the market when Defendants knew or should have known of the likelihood of serious side effects, injury and death to its users.
- g. Failing to adequately warn users, consumers and physicians about the severity, scope and likelihood of bleeds and related dangerous conditions to individuals taking Pradaxa®.
- h. Failing to adequately and clearly warn that Pradaxa® induced bleeds are irreversible and have no antidote in the "*Warnings and Precautions*" section of the product label until January 2012.
- i. Burying the fact that there is no antidote for Pradaxa® in obscure, confusing and inadequate language contained in the "*Overdosage*" section of the product label until January 2012.
- j. Representing to physicians, including Plaintiff's prescribing physicians, that this drug was safe and effective for use.



- k. Failing to provide for patient-specific dosing, despite Defendants' knowledge that patients eliminate Pradaxa® from their bodies at different rates, and their knowledge that approximately ten percent of patients are "super absorbers" who eliminate Pradaxa® from their bodies slower than other patients.
  - l. Failing to seek approval of said reversal agent from the FDA until February 19, 2015, despite having actually had developed a reversal agent for Pradaxa®-induced bleeds prior to the time Pradaxa® was approved for sale in the United States.
  - m. Failing to provide physicians and patients with an accurate test to monitor the level of Pradaxa® in a patient's blood despite the fact that Pradaxa® has a narrow therapeutic window and is only effective if dosed properly for each individual patient.
131. The Pradaxa® that injured Plaintiffs was in substantially the same condition when they ingested it as it was in when it left the control of Defendants, and Plaintiffs consumed the Pradaxa® as directed and without change in its form or substance.
132. The evidence will establish that such failures were a proximate cause of the injuries and damages to Plaintiffs herein.
133. Plaintiffs seek all damages to which they may be justly entitled.

**COUNT IV**  
**BREACH OF IMPLIED WARRANTY**

134. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
135. Defendants designed, manufactured, marketed, distributed, supplied and sold Pradaxa® for the treatment of atrial fibrillation.
136. At the time that Defendants manufactured, marketed, distributed, supplied and sold Pradaxa®, they knew of the use for which the subject product was intended and impliedly warranted it to be merchantable quality and safe and fit for such use.

137. The Plaintiffs, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants.
138. The Plaintiffs were prescribed, purchased and used Pradaxa® for its intended purpose.
139. Due to the Defendants' wrongful conduct as alleged herein, the Plaintiffs could not have known about the nature of the risks and side effects associated with the subject product until after they used it.
140. Contrary to the implied warranty for the subject product, Pradaxa® was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.
141. As a direct and proximate result of Defendants' breach of implied warranty, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.
142. Plaintiffs seek all damages to which they may be justly entitled.

**COUNT V**  
**BREACH OF EXPRESS WARRANTY**

143. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
144. At all times hereinafter mentioned, upon information and belief, Defendants, by direct and indirect advertising, marketing and promoting Pradaxa® for the treatment of atrial fibrillation, and by placing this drug in the stream of commerce knowing that Pradaxa® would be prescribed for the treatment of atrial fibrillation in reliance upon the representations of Defendants, expressly warranted to all foreseeable users of this drug, including the Plaintiffs, that Pradaxa® was safe and effective for the treatment of atrial fibrillation.

145. At all times hereinafter mentioned, Plaintiffs relied upon the aforesaid express and implied warranties by Defendants.
146. At all times hereinafter mentioned, Plaintiffs' use of Pradaxa® prior to and up to the time of the above-described incidents was consistent with the purposes for which Defendants directly and indirectly advertised, marketed and promoted Pradaxa®, and Plaintiffs' use of Pradaxa® was reasonably contemplated, intended and foreseen by Defendants at the time of the distribution and sale of Pradaxa® by Defendants, and, therefore, Plaintiffs' use of Pradaxa® was within the scope of the above-described express and implied warranties.
147. Defendants breached the aforesaid express and implied warranties because Pradaxa® was not safe and effective for the treatment of atrial fibrillation, and because Plaintiffs' use of Pradaxa® for the treatment of atrial fibrillation caused or contributed their injuries described herein.
148. As a direct and proximate result of Defendants breach of express warranty, the Plaintiffs suffered severe and permanent physical injuries which are continuing in nature.
149. Plaintiffs seek all damages to which they may be justly entitled.

**COUNT VI**  
**MISREPRESENTATION**

150. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
151. Defendants made material representations which were false, knowing that such representations were false and/or with reckless disregard for the truth or falsity of such representations, with the intent that Plaintiffs and their physicians would rely on such material representations. Plaintiffs and their physicians acted in actual and justifiable

reliance on such material misrepresentations, and that Plaintiffs were seriously injured as a result thereof.

152. In addition, and in the alternative if necessary, Defendants withheld relevant and material information regarding the true risks associated with the use of Pradaxa®, with the intent that Plaintiffs and their physicians would rely on Defendants' misrepresentations. The evidence will establish that Plaintiffs and their physicians acted in actual and justifiable reliance on Defendants' representations, and that Plaintiffs were injured as a result thereof.
153. Defendants made these misrepresentations at a time when the Defendants knew, or should have known, that Pradaxa® had defects, dangers, and characteristics that were other than those Defendants represented to patients and the healthcare industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs and their physicians information pertaining to the risk of developing irreversible and potentially fatal bleeds and life-threatening conditions.
154. Defendants perpetuated the misrepresentations and/or active concealments alleged herein, directly and/or indirectly. Defendants knew or should have known these representations were false and made the representations with the intent or purpose that Plaintiffs and their physicians would rely on them, leading to the use of Pradaxa®.
155. At the time of Defendants' fraudulent misrepresentations, Plaintiffs and their physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs and their physicians had no knowledge of the information concealed and/or suppressed by Defendants, and they justifiably relied on and/or were induced by these misrepresentations, and relied on the absence of real safety information to Plaintiffs'

detriment. Such misrepresentations were a direct and proximate cause of Plaintiffs' injuries.

**COUNT VII**  
**UNJUST ENRICHMENT**

156. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
157. As an intended and expected result of its conscious wrongdoing, Defendants have profited and benefited from the sales of Pradaxa® to Plaintiffs and the public.
158. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiffs and others, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs did not receive a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiffs, as reasonable consumers, expected.
159. By virtue of the conscious wrongdoing alleged in this complaint, Defendants have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek the disgorgement and restitution of Defendants' wrongful profits, revenue and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as this Court deems just and proper to remedy the Defendants' unjust enrichment.

**COUNT VIII**  
**GROSS NEGLIGENCE**

160. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.

161. Plaintiffs further show the negligent acts and/or omissions of Defendants, as set forth above, constitute an entire want of care and conscious indifference and/or malice so as to give rise to the award of exemplary damages.
162. Plaintiff show that the negligent acts and/or omissions of Defendants, as set forth above, constitute acts or omissions:
- a. Which, when viewed objectively from the standpoint of Defendants, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to Plaintiffs, and
  - b. Of which Defendants had actual, subjective awareness of the risks involved, but nevertheless proceeded with conscious indifference to the rights, safety or welfare of Plaintiffs.
163. The gross negligence of the Defendants was a proximate cause of the injuries, damages, and deaths suffered by Plaintiff.

**COUNT IX**  
**DAMAGES**

164. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
165. As a result of the above-described acts and omissions of these Defendants, Plaintiffs have incurred actual damages in excess the jurisdictional limit of this Court including, but not limited to:
- a. Reasonable and necessary medical expenses incurred in the past;
  - b. Conscious physical pain and suffering experienced in the past;
  - c. Mental anguish in the past;
  - d. Mental anguish likely to be experienced in the future;
  - e. Wrongful death;
  - f. Post-judgment interest at the lawful rate;

- g. Exemplary damages;
- h. Such other applicable damages, as the Court deems appropriate.

### **PUNITIVE DAMAGES**

- 166. Plaintiffs incorporate by reference all preceding paragraphs and all factual allegations contained therein.
- 167. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their product, including Plaintiffs, with full knowledge of Pradaxa®'s true safety and efficacy and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.
- 168. Defendants' conduct was intentional and/or wanton.
- 169. Defendants conduct as described above, including, but not limited to, its failure to adequately test the product, to provide adequate warnings, and its continued manufacture, sale, and marketing of the product when it knew or should have known of the serious health risks created, was intentional, willful wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendants acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiffs. Accordingly, punitive damages should be imposed against Defendants to punish and deter Defendant from repeating or continuing such unlawful conduct.

### **PRAYER**

WHEREFORE, Plaintiffs pray that upon final determination of these causes of action, Plaintiffs receives a judgment against the Defendants as follows:

- (a) That process issue according to law;
- (b) That Defendants be served with a copy of Plaintiffs' Complaint For Damages and show cause why the prayers for relief requested by Plaintiffs herein should not be granted;
- (c) That Plaintiffs be granted a **trial by jury** in this matter;
- (d) That the Court enter a judgment against Defendants for all general and compensatory damages allowable to Plaintiffs;
- (e) That the Court enter a judgment against Defendants for all special damages allowable to Plaintiffs;
- (f) That the Court enter a judgment against Defendants serving to award Plaintiffs punitive damages;
- (g) That the Court enter a judgment against Defendants for all other relief sought by Plaintiffs under this Complaint;
- (h) That the costs of this action be cast upon Defendants; and
- (i) That the Court grant Plaintiffs such further relief which the Court deems just and appropriate.

**JURY DEMAND**

Plaintiffs hereby demand a trial by jury on all issues so triable.



DATED: November 16, 2015

Respectfully submitted,

CAREY DANIS & LOWE

By: /s/ Jeffrey J. Lowe  
Jeffrey J. Lowe, Esq. #35114MO  
John F. Garvey, Jr. #35879MO  
Sarah Shoemake Doles #45747MO  
8235 Forsyth Boulevard, Suite 1100  
Clayton, Missouri 63105  
[jlowe@careydanis.com](mailto:jlowe@careydanis.com)  
[jgarvey@careydanis.com](mailto:jgarvey@careydanis.com)  
[sdoles@careydanis.com](mailto:sdoles@careydanis.com)  
(314) 725-7700  
(314) 678-3401 (facsimile)

THE GALLAGHER LAW FIRM, LLP

/s/ Michael T. Gallagher  
Michael T. Gallagher # 07586000TX  
2905 Sackett Street  
Houston, Texas 77098  
(713) 222-8080  
[pamm@gld-law.com](mailto:pamm@gld-law.com)

CHILDERS, SCHLUETER & SMITH, LLC

/s/ C. Andrew Childers  
C. Andrew Childers #124398GA  
1932 N. Druid Hills Road, Suite 100  
Atlanta, Georgia 30319  
(404) 419-9500 - phone  
(404) 419-9501 - facsimile  
[achilders@cssfirm.com](mailto:achilders@cssfirm.com)

NEMEROFF LAW FIRM

/s/ Ellen A. Presby

Ellen A Presby 16249600TX

2626 Cole Ave., Suite 450

Dallas, TX 75204

(214) 774-2258

(214) 393-7897 Fax

[EllenPresby@NemeroffLaw.com](mailto:EllenPresby@NemeroffLaw.com)

**ATTORNEYS FOR PLAINTIFFS**

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that the foregoing was filed using the Court's electronic filing system and thereby served upon all registered counsel of record by electronic filing on the 16<sup>th</sup> day of November, 2015.

\_\_\_\_\_/s/ Jeffrey J. Lowe